



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-0266]

Identification of Medicinal Products--Implementation and Use; Guidance for Industry;  
Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled “Identification of Medicinal Products--Implementation and Use.” This guidance explains FDA’s position and progress on aligning the Agency’s standards to Identification of Medicinal Products (IDMP) standards, which the Agency supports, to identify and describe marketed medicinal products with the exception of investigational medicinal products, with the goal of harmonizing the standards for the international exchange of medicinal product data. The guidance is intended to assist sponsors, applicants, and registrants who are involved in the regulatory submission of medicinal product data.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2023-D-0266 for "Identification of Medicinal Products--Implementation and Use." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information

you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ta-Jen Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1196, Silver Spring, MD 20993-0002, 301-796-7921, Ta-jen.chen@fda.hhs.gov; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a guidance for industry entitled “Identification of Medicinal Products--Implementation and Use.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because the harmonization of global IDMP implementation is a process whereby regulatory recommendations across different countries or regions become aligned over time using international guidance documents, consensus standards, policies, and procedures. This guidance presents a least burdensome policy to advance international harmonization by using the most efficient means to achieve regulatory goals. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation.

The guidance supports the development and implementation of the International Organization for Standardization (ISO) IDMP standards for substances, terminologies, and other information for use throughout the global medicinal product development lifecycle. In 2013, FDA established an internal committee to determine the conformance of FDA standards to the ISO IDMP standards. Over several years, the committee analyzed the structure, format, and content of the Unique Ingredient Identifier, Structured Product Labeling Pharmaceutical Dosage

Form Terminology, Unified Code for Units of Measure, and National Drug Code to assess their conformance to ISO 11238, ISO 11239, ISO 11240, and ISO 11615, respectively. FDA's internal committee determined that the Agency's standards conform to the ISO IDMP standards for regional use. Topics covered in this guidance include:

- Introduction and scope
- Introduction to the five ISO IDMP standards: ISO 11238 (substance), ISO 11239 (dose form), ISO 11240 (units of measure), ISO 11615 (medicinal product identification), and ISO 11616 (pharmaceutical product identification)
- Benefits of IDMP implementation and use, including drug safety and pharmacovigilance, medicinal product traceability for global supply chain integrity, and regulatory registration and exchange of medicinal product information
- FDA's approach to the IDMP standards
- Phased approach to the global implementation

The guidance represents the current thinking of FDA on "Identification of Medicinal Products--Implementation and Use." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information->

biologics/biologics-guidances, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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